

*Amendment and Response to Office Action
U.S. Application Serial No. 10/635,428
Page 7*

REMARKS

Upon entry of this amendment, Claims 1, 3-14, 18-22, 24-27 and 29 will be pending in this application. Claims 2 and 28 have been cancelled without prejudice. Claims 1, 13, 18, 21, 26, 27 and 29 have been amended. No new matter is added and support for the amendments is found on page 14, lines 16-19 of the specification. Applicant's representative thanks the Examiner for extending the courtesy of a telephone interview on June 1, 2006. During the interview, the outstanding rejection and possible claim amendments were discussed.

Rejection of Claims 1-14, 18-22 and 24-29 under 35 U.S.C. §103(a)

In the Office Action mailed February 7, 2006, The Examiner rejects claims 1-14, 18-22 and 24-29 under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0 595 005 A1 (hereinafter the European Patent) in view of Klevay *et al.* (American Journal of Clinical Nutrition, Vol. 75, No. 3, 550-554, March 2002, hereinafter Klevay). Claims 2 and 28 are cancelled, rendering moot their rejection.

The Examiner asserts that the European Patent teaches administration of a composition consisting of vitamin B12, vitamin B6, folic acid, with an antioxidant such as vitamin E, but does not teach the use of magnesium. The Examiner asserts that Klevay teaches the importance of magnesium in protecting against vascular disease and therefore one of ordinary skill in the art would be motivated to add magnesium to the composition disclosed in the European Patent in order to derive Applicant's claimed composition. Applicant respectfully traverses and asserts that the claim amendments and the following remarks overcome the rejection and request its withdrawal.

Amendment and Response to Office Action
U.S. Application Serial No. 10/635,428
Page 8

In the introduction, Klevay makes general statements about magnesium counteracting harmful processes that lead to death from ischemic heart disease. Klevay is concerned with dietary intake of magnesium and discloses various sequelae, such as supraventricular arrhythmias (ventricular tachycardia and fibrillation) that may occur in states of low levels of magnesium. Klevay's experimental research is concerned with electrophysiological measurements of myocardial irritability in individuals on low magnesium diets, as evidenced by ectopic beats detected with Holter monitors. Klevay is not concerned with vascular disease or its treatment and prevention. Accordingly, Klevay is in a different field (electrophysiological analysis of low magnesium levels on supraventricular and ventricular beats) than the European Patent. Applicant respectfully asserts that the combination of these references is improper. One of ordinary skill in the art of preparing vitamin compositions and administering them to treat or prevent vascular disease would not look to Klevay for guidance and would not combine Klevay with the European patent. For at least these reasons, Applicant asserts that the rejection under §103(a) is improper and requests its withdrawal.

Further, Klevay does not provide any motivation or suggestion to make a vitamin composition by adding magnesium to vitamin B12, vitamin B6, folic acid, and vitamin E and derive Applicant's composition. Klevay is not concerned with vitamin compositions and their use. Klevay discloses that diets low in magnesium can disrupt magnesium homeostasis as detected through various chemical and physiological indicators. Klevay shows that supplementation with a capsule of 200 mg/day of magnesium is required to maintain magnesium levels above the recommended daily allowance in middle-aged women consuming a low magnesium diet. Klevay is not concerned with preparation of vitamin compositions for treating

Amendment and Response to Office Action
U.S. Application Serial No. 10/635,428
Page 9

or preventing vascular disease. Accordingly, Klevay does not teach or suggest anything related to magnesium beyond that which is necessary to meet the recommended daily allowance of magnesium in individuals consuming a low magnesium diet. The reference does not teach, suggest or provide motivation to combine magnesium with anything else and administer the combination to treat or prevent vascular disease.

Applicant believes that the obviousness rejection is improper and requests its withdrawal. Nevertheless, in the interests of advancing prosecution, the claims have currently been amended without prejudice, to recite a composition containing between about 75 mg and 150 mg of magnesium. Support for the amendment can be found in the specification on page 14, lines 16-19. Since Klevay discloses only supplementation with an amount of magnesium (200 mg/day) effective to maintain magnesium homeostasis in individuals receiving a magnesium deficient diet, Klevay, alone or in combination with the European Patent, does not teach, suggest or provide motivation to one of ordinary skill in the art to derive Applicant's claimed vitamin composition, consisting of vitamin B12, vitamin B6, folic acid, vitamin E and between about 75 mg to 150 mg of magnesium, or to use it to treat or prevent vascular disease.

For at least the reasons presented above, Applicant respectfully asserts that the rejection of claims 1, 3-14, 18-22, and 24-27 and 29 under 35 U.S.C. §103(a) has been overcome and requests its withdrawal.

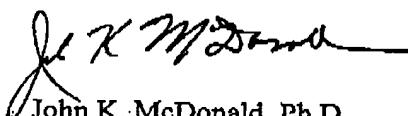
Amendment and Response to Office Action
U.S. Application Serial No. 10/635,428
Page 10

CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed February 7, 2006. Applicant asserts that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 745-2470 is respectfully requested.

No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account number 11-0855.

Respectfully submitted,



John K. McDonald, Ph.D.
Reg. No. 42,860

KILPATRICK STOCKTON LLP
Suite 2800, 1100 Peachtree Street
Atlanta, GA 30309-4530
Telephone: 404-815-6500
Facsimile: 404-815-6555
Attorney Docket No. 52761-0100 (285976)